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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,967	02/27/2004	Joseph Anthony Gatto	8725R2R	9429

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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06/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,967	Applicant(s) GATTO, JOSEPH ANTHONY	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/27/04;2/3/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/27/04 and 2/3/06 have been received and acknowledged. However, the non-patent literature on sheet 2/2 with a received date of 2/3/06 has been lined through as a search report is not a non-patent literature. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", "at least about" and "less than about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of

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the invention, because one of skill will not be able to determine which term is in control.

The claims lack clarity as to whether "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "at least about". Regarding "less than" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about".

Claims 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", "at least about" and "less than about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "at least about". Regarding "less than" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about".

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Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a solid skin treatment agent" and claim 2 recites "a skin care agent". Is the skin care agent and the solid skin treatment agent the same? Skin care agents does not have to result in a solid skin treatment agent.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "skin care agent" in claim 1. There is insufficient antecedent basis for this limitation in the claim as explained regarding skin care agent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of the structure of a representative number of derivative compounds of vitamin C nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Applicant should note with regards to the below rejection, no patentability weight has been given to the method of preparing, once the product is found to be the same it inherently comprises of the claimed characteristics. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In

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such a situation the burden is shifted to the applicants to "prove that the subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second first full para.).

Claims 2, 5 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The above listed claims recite derivatives of Chitosan (see claim 20, guanidinobenzoic (see claims 5 and 14) by incorporation (see page 9, lines 18-20 and 27-30).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1,5, 11, 14, 19 and 20** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1– 22** of U.S. Patent Application No. **10992383**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The copending application recite the steps of the instant claims wherein it provides a carrier system identified as petrolatum, as in the instant claim, having a temperature of at least 35 degrees C , comprising a chitosan having the same properties (see claims 1-2 of instant and claim 1 of copending) used as a as a sanitary napkin in claims 20 and 22 of the copending application. The claims differ in that the steps involved in the copending application comprises of 4 steps and in the instant application three steps.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn, III et al. US 6,409,713 taken with Lin US 2002/0115968 A1 in view of Gatto et al. US 6,793,930 and Roe et al. US 6,703,536 B2

With regards to claims 1, 3 and 11-12, Osborn, III et al. teach an absorbent device comprising an emollient such as petrolatum (see abstract), wherein the emollient is 37 degrees C (see col. 16, lines 29-34) with a melting of 35 degrees C (see col. 20, lines 25) further comprising fatty alcohols, fatty acid wherein the carbon content is from 12-24 (see col. 17, lines 27-38) as in claims 4 and 13. The reference further teaches the temperature ranges from 50-150 degrees C (see col. 20, lines 23-30) as in claims 6-9 and 15-17. The reference teaches miscible-which has been interpreted by the Examiner to mean from basic chemistry, property of various substances that allows them to be mixed together absent factual evidence or as evident by General Chemistry Online enclosed. Although, Osborn III et al. did not teach explicitly with regards to instant claim 19-20 a diaper, the reference however, teaches an absorbent device worn by female wearers having the said properties of above and as depicted by Figures 1-12 a tampon.

Lin teaches chitosan in a skin care absorbing article (see abstract) a diaper (see diagram front page).

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Gatto et al. also teach with regards to instant claims 1(part c),11 (part c), 10 and 18 the reference teaches a skin care composition (see abstract) having the characteristics wherein the particle size of the skin care agent is less than 100 microns (see col. 11, lines 35-50) results from milling (see col. 11, lines 45-50). The reference also teaches with regards to claims 5 and 14 a skin care composition comprising fatty acid having carbon atoms from 12-28 (see col. 16, lines34), and the carrier is of petrolatum (see col. 16, lines 45-49) wherein the composition can further comprise vitamins (see col. 24, line 57) as in claims 5 and 11. Gato et al. also teaches with regards to instant claim 19-20 a diaper see Fig. I

Roe et al. teach an absorbent article comprising protease inhibitors such as metalloprotease, cysteine (see col. 6, lines 33-39), wherein the composition further comprises petrolatum (see col. 27, lines 30-31) and fatty acids and fatty alcohols (see col. 27, lines 40-67 and col. 28, lines 3-10), vitamins (see col. 35, line 44). Roe et al. also teach the absorbent particle liner is a diaper (see col. 1, lines 16-17) as in claims 19-20.

The combined cited art teaches the claimed invention, therefore one of ordinary skill in the art would be motivate to make a sanitary napkin or a diaper that has all these properties because each of the sited art cited has incorporated the claimed invention in whole or in part to a product that is used as a hygiene skin care or an absorbent article for the skin. Thus motivating one of ordinary skill in the art to combine and optimize.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
6/13/07


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SUPERVISORY PATENT EXAMINER